

CLAIMS:

1. An elongated medical instrument to be advanced through the body comprising:
an instrument body extending between an instrument body proximal end and an
5 instrument body distal end and having an instrument body proximal segment and an
instrument body distal segment, the instrument body having an instrument body axis extending
axially in the instrument body distal segment and further comprising an elongated pull wire
lumen extending through the instrument body proximal segment and instrument body distal
10 segment, the pull wire lumen extending in parallel with and radially offset in a first radial
direction from the instrument body distal axis in the instrument body distal segment;
an inelastic pull wire extending through the pull wire lumen from a pull wire proximal
attachment with the elongated medical instrument to a pull wire distal attachment with the
instrument body distal segment; and
the instrument body proximal segment is formed of an elastic material capable of being
15 stretched axially under axially applied tension, whereby the inelastic pull wire bends in the
first radial direction and thereby imparts a curve to the instrument body in the instrument body
distal segment.
2. The elongated medical instrument of Claim 1, wherein the instrument body
20 further comprises means for restraining the length of the curve imparted in the instrument body
distal segment.
3. The elongated medical instrument of Claim 2, further comprising proximal
tension applying means coupled to the instrument body proximal segment at a proximal site of
25 the instrument body proximal segment and distal tension applying means coupled to the
instrument body proximal segment at a distal site of the instrument body proximal segment,
the proximal and distal tension applying means separated apart by a relaxed length of the
instrument body proximal segment, wherein tension is adapted to be applied axially between
the proximal and distal tension applying means and transferred to the instrument body
30 proximal segment to stretch it to a tensioned length of the instrument body proximal segment
exceeding the relaxed length.

4. The elongated medical instrument of Claim 1, further comprising proximal tension applying means coupled to the instrument body proximal segment at a proximal site of the instrument body proximal segment and distal tension applying means coupled to the instrument body proximal segment at a distal site of the instrument body proximal segment, the proximal and distal tension applying means separated apart by a relaxed length of the instrument body proximal segment, wherein tension is adapted to be applied axially between the proximal and distal tension applying means and transferred to the instrument body proximal segment to stretch it to a tensioned length of the instrument body proximal segment exceeding the relaxed length.

5. The elongated medical instrument of Claim 1, wherein the instrument body further comprises an elongated stylet lumen extending from a stylet lumen proximal end opening through the instrument body proximal segment and instrument body distal segment to a stylet distal end, the stylet lumen extending in parallel with and radially offset in a second radial direction from the instrument body distal axis in the instrument body distal segment, whereby a relatively straight stylet wire of a stylet can be inserted through the stylet lumen proximal end opening and advanced distally through a selected proximal portion of the instrument body distal segment to constrain the formation of the curve to the distal portion of the instrument body distal segment.

6. The elongated medical instrument of Claim 5, wherein the instrument body in the instrument body proximal segment has an instrument body diameter and further comprising an enlarged diameter proximal tension applying ring coupled to the instrument body proximal segment at a proximal site of the instrument body proximal segment and an enlarged diameter distal tension applying ring coupled to the instrument body proximal segment at a distal site of the instrument body proximal segment, the proximal and distal tension applying rings separated apart by a relaxed length of the instrument body proximal segment, wherein tension is adapted to be applied axially between the proximal and distal tension applying rings and transferred to the instrument body proximal segment to stretch it to a tensioned length of the instrument body proximal segment exceeding the relaxed length.

7. The elongated medical instrument of Claim 1, wherein the instrument body in the instrument body proximal segment has an instrument body diameter and further comprising an enlarged diameter proximal tension applying ring coupled to the instrument body proximal segment at a proximal site of the instrument body proximal segment
5 and an enlarged diameter distal tension applying ring coupled to the instrument body proximal segment at a distal site of the instrument body proximal segment, the proximal and distal tension applying rings separated apart by a relaxed length of the instrument body proximal segment, wherein tension is adapted to be applied axially between the proximal and distal tension applying rings and transferred to the instrument body proximal segment to stretch it to
10 a tensioned length of the instrument body proximal segment exceeding the relaxed length.

8. The elongated medical instrument of Claim 1, wherein the medical instrument comprises an electrical medical lead.

15 9. The elongated medical instrument of Claim 1, wherein the medical instrument comprises a guide wire.

10 10. The elongated medical instrument of Claim 1, wherein the medical instrument comprises a catheter.

20 11. An elongated electrical medical lead to be advanced through the body comprising:

a lead body extending between a lead body proximal end and a lead body distal end and having a lead body proximal segment and a lead body distal segment, the lead body having a
25 lead body axis extending axially in the lead body distal segment and further comprising an elongated pull wire lumen extending through the lead body proximal segment and lead body distal segment, the pull wire lumen extending in parallel with and radially offset in a first radial direction from the lead body distal axis in the lead body distal segment;

a proximal connector element at the lead body proximal end;

30 an electrode at the lead body distal end;

an elongated electrical conductor extending between the proximal connector element and the electrode through and enclosed within the lead body;

an inelastic pull wire extending through the pull wire lumen from a pull wire proximal attachment with the elongated medical lead to a pull wire distal attachment with the lead body distal segment; and

the lead body proximal segment is formed of an elastic material capable of being stretched axially under axially applied tension, whereby the inelastic pull wire bends in the first radial direction and thereby imparts a curve to the lead body in the lead body distal segment to orient the electrode at a desired site in the body.

12. The elongated medical lead of Claim 11, wherein the lead body further comprises means for restraining the length of the curve imparted in the lead body distal segment.

13. The elongated medical lead of Claim 12, further comprising proximal tension applying means coupled to the lead body proximal segment at a proximal site of the lead body proximal segment and distal tension applying means coupled to the lead body proximal segment at a distal site of the lead body proximal segment, the proximal and distal tension applying means separated apart by a relaxed length of the lead body proximal segment, wherein tension is adapted to be applied axially between the proximal and distal tension applying means and transferred to the lead body proximal segment to stretch it to a tensioned length of the lead body proximal segment exceeding the relaxed length.

14. The elongated medical lead of Claim 11, further comprising proximal tension applying means coupled to the lead body proximal segment at a proximal site of the lead body proximal segment and distal tension applying means coupled to the lead body proximal segment at a distal site of the lead body proximal segment, the proximal and distal tension applying means separated apart by a relaxed length of the lead body proximal segment, wherein tension is adapted to be applied axially between the proximal and distal tension applying means and transferred to the lead body proximal segment to stretch it to a tensioned length of the lead body proximal segment exceeding the relaxed length.

15. The elongated medical lead of Claim 11, wherein the lead body further comprises an elongated stylet lumen extending from a stylet lumen proximal end opening through the lead body proximal segment and lead body distal segment to a stylet distal end, the stylet lumen extending in parallel with and radially offset in a second radial direction from the lead body distal axis in the lead body distal segment, whereby a relatively straight stylet wire of a stylet can be inserted through the stylet lumen proximal end opening and advanced distally through a selected proximal portion of the lead body distal segment to constrain the formation of the curve to the distal portion of the lead body distal segment.

16. The elongated medical lead of Claim 15, wherein the lead body in the lead body proximal segment has a lead body diameter and further comprising an enlarged diameter proximal tension applying ring coupled to the lead body proximal segment at a proximal site of the lead body proximal segment and an enlarged diameter distal tension applying ring coupled to the lead body proximal segment at a distal site of the lead body proximal segment, the proximal and distal tension applying rings separated apart by a relaxed length of the lead body proximal segment, wherein tension is adapted to be applied axially between the proximal and distal tension applying rings and transferred to the lead body proximal segment to stretch it to a tensioned length of the lead body proximal segment exceeding the relaxed length.

17. The elongated medical lead of Claim 15, wherein the elongated electrical conductor extends through the stylet wire lumen.

18. The elongated medical lead of Claim 17, further comprising:
a further proximal connector element at the lead body proximal end;
a further electrode at the lead body distal end; and
wherein the pull wire is formed of a conductive material and is attached to the further proximal connector element and the further electrode and functions as a lead conductor.

19. The elongated medical lead of Claim 11, further comprising:
a further proximal connector element at the lead body proximal end;
a further electrode at the lead body distal end; and
wherein the pull wire is formed of a conductive material and is attached to the further
5 proximal connector element and the further electrode and functions as a lead conductor.

20. The elongated medical lead of Claim 11, wherein the lead body in the lead body
proximal segment has a lead body diameter and further comprising an enlarged diameter
proximal tension applying ring coupled to the lead body proximal segment at a proximal site
10 of the lead body proximal segment and an enlarged diameter distal tension applying ring
coupled to the lead body proximal segment at a distal site of the lead body proximal segment,
the proximal and distal tension applying rings separated apart by a relaxed length of the lead
body proximal segment, wherein tension is adapted to be applied axially between the proximal
and distal tension applying rings and transferred to the lead body proximal segment to stretch it
15 to a tensioned length of the lead body proximal segment exceeding the relaxed length.

21. A system for advancing an elongated medical instrument through the body
comprising:

an elongated medical instrument comprising:
20 an instrument body extending between an instrument body proximal end and an
instrument body distal end and having an instrument body proximal segment and an
instrument body distal segment, the instrument body having an instrument body axis
extending axially in the instrument body distal segment and further comprising an
elongated pull wire lumen extending through the instrument body proximal segment and
25 instrument body distal segment, the pull wire lumen extending in parallel with and radially
offset in a first radial direction from the instrument body distal axis in the instrument body
distal segment; and
an inelastic pull wire extending through the pull wire lumen from a pull wire
proximal attachment with the elongated medical instrument to a pull wire distal attachment
30 with the instrument body distal segment;

the instrument body proximal segment is formed of an elastic material capable of being stretched axially under axially applied tension, whereby the inelastic pull wire bends in the first radial direction and thereby imparts a curve to the instrument body in the instrument body distal segment; and

5 proximal tension applying means coupled to the instrument body proximal segment at a proximal site of the instrument body proximal segment and distal tension applying means coupled to the instrument body proximal segment at a distal site of the instrument body proximal segment, the proximal and distal tension applying means separated apart by a relaxed length of the instrument body proximal segment,

10 tool means for engaging and applying tension axially between the proximal and distal tension applying means to stretch the instrument body proximal section to a tensioned length exceeding the relaxed length.

22. The system of Claim 21, wherein the tool means further comprises means for
15 restraining the tensioned length of the instrument body proximal segment.

23. The system of Claim 21, wherein the instrument body further comprises an elongated stylet lumen extending from a stylet lumen proximal end opening through the instrument body proximal segment and instrument body distal segment to a stylet distal end,
20 the stylet lumen extending in parallel with and radially offset in a second radial direction from the instrument body distal axis in the instrument body distal segment, whereby a relatively straight stylet wire of a stylet can be inserted through the stylet lumen proximal end opening and advanced distally through a selected proximal portion of the instrument body distal segment to constrain the formation of the curve to the distal portion of the instrument body
25 distal segment.

24. The system of Claim 21, wherein:
the instrument body in the instrument body proximal segment has an instrument body diameter;

the proximal tension applying means further comprises an enlarged diameter proximal tension applying ring coupled to the instrument body proximal segment at a proximal site of the instrument body proximal segment;

the distal tension applying means further comprises an enlarged diameter distal tension
5 applying ring coupled to the instrument body proximal segment at a distal site of the instrument body proximal segment; and

the tool means is adapted to engage and increase the separation between the proximal and distal tension applying rings to stretch the instrument body proximal segment to the tensioned length.

10

25. The system of Claim 21, wherein the medical instrument comprises an electrical medical lead.

15

26. The system of Claim 21, wherein the medical instrument comprises a guide wire.

27. The system of Claim 21, wherein the medical instrument comprises a catheter.

20

28. A system for advancing an elongated medical instrument through the body comprising:

an elongated medical instrument comprising:

25

an instrument body extending between an instrument body proximal end and an instrument body distal end and having an instrument body proximal segment and an instrument body distal segment, the instrument body having an instrument body axis extending axially in the instrument body distal segment and further comprising an elongated pull wire lumen extending through the instrument body proximal segment and instrument body distal segment, the pull wire lumen extending in parallel with and radially offset in a first radial direction from the instrument body distal axis in the instrument body distal segment; and

an inelastic pull wire extending through the pull wire lumen from a pull wire proximal attachment with the elongated medical instrument to a pull wire distal attachment with the instrument body distal segment;

5 the instrument body proximal segment is tubular having a predetermined segment diameter and is formed of an elastic material capable of being stretched axially under axially applied tension, whereby the inelastic pull wire bends in the first radial direction and thereby imparts a curve to the instrument body in the instrument body distal segment;

an enlarged diameter proximal tension applying ring coupled to the instrument body proximal segment at a proximal site of the instrument body proximal segment; and

10 an enlarged diameter distal tension applying ring coupled to the instrument body proximal segment at a distal site of the instrument body proximal segment and separated from the proximal tension applying ring by a relaxed length of the instrument body proximal segment; and

15 a hand-held tool having a first surface that engages the proximal tension applying ring and a second surface spaced from the first surface that engages the distal tension applying ring and a spanner extending between the first and second surfaces that can be manually adjusted to increase the spacing between the first and second surfaces to axially apply tension to and increase the length of the instrument body proximal segment.

20 29. The system of Claim 28, wherein the hand-held tool further comprises a frame that supports a fixed cradle having a notch sized to receive the diameter of the instrument body proximal segment between the proximal and distal tension applying rings and supports a shuttle movable along the frame with respect to the fixed cradle, the shuttle having a notch sized to receive the diameter of the instrument body proximal segment between the proximal
25 and distal tension applying rings, whereby one of the fixed cradle and the shuttle present the first surface to the proximal tension applying ring and the other of the fixed cradle and the shuttle presents the second surface to the distal tension applying ring, the frame supporting the cradle and shuttle functions as the spanner between the first and second surfaces, and the shuttle is manually movable along the frame to increase the spacing between the first and
30 second surfaces to axially apply tension to and increase the length of the instrument body proximal segment.

30. The system of Claim 29, wherein the hand-held tool further comprises a movable stop supported by the frame in the path of movement of the movable shutter that is adjustable to limit the maximum spacing that can be made between the first and second surfaces.

5

31. The system of Claim 29, wherein the hand-held tool further comprises a spring load that limits the maximum tension that can be applied made between the proximal and distal rings.

10

32. The system of Claim 28, wherein the spanner of the hand-held tool further comprises first and second elongated spring bands that extend between opposed first and second sides of first and second extension blocks, the first and second extension blocks present the first and second surfaces respectively parallel to one another, the first and second extension blocks having first and second slots, respectively, extending laterally across the first and second extension blocks intersecting the first and second surfaces and sized to receive the diameter of the instrument body proximal segment between the proximal and distal tension applying rings and to present the first surface to the proximal tension applying ring and the second surface to the distal tension applying ring, whereby the first and second surfaces are spread apart as the elongated spring bands are pressed toward one another to axially apply tension to and increase the length of the instrument body proximal segment.

15
20

33. The system of Claim 32, wherein the spanner further comprises third and fourth spring bands extending between opposed third and fourth sides of the first and second extension blocks, whereby the first and second surfaces are spread apart as the first and second elongated spring bands are pressed toward one another and the third and fourth spring bands are pressed toward one another to axially apply tension to and increase the length of the instrument body proximal segment.

25

30

34. A method of advancing an elongated medical instrument through the body comprising:

inserting the elongated medical instrument into a pathway of the body, the elongated medical instrument comprising:

- 5 an instrument body extending between an instrument body proximal end and an instrument body distal end and having an instrument body proximal segment and an instrument body distal segment, the instrument body having an instrument body axis extending axially in the instrument body distal segment and further comprising an
- 10 elongated pull wire lumen extending through the instrument body proximal segment and instrument body distal segment, the pull wire lumen extending in parallel with and radially offset in a first radial direction from the instrument body distal axis in the instrument body distal segment;
- an inelastic pull wire extending through the pull wire lumen from a pull wire proximal attachment with the elongated medical instrument to a pull wire distal attachment
- 15 with the instrument body distal segment; and
- the instrument body proximal segment is formed of an elastic material capable of being stretched axially under axially applied tension; and
- as the distal end is advanced, selectively applying tension axially to stretch the instrument body proximal segment whereby the inelastic pull wire bends in the first radial
- 20 direction and thereby imparts a curve to the instrument body in the instrument body distal segment so as to deflect the distal end to the extent found expedient to advance the distal tip and to position the distal end at a remote site in the body.

35. The method of advancing an elongated medical instrument of Claim 34, further comprising:

selectively restraining the length of the curve imparted in the instrument body distal segment to effect the advancement and positioning of the distal end.

36. The method of advancing an elongated medical instrument of Claim 34, wherein the instrument body further comprises an elongated stylet lumen extending from a stylet lumen proximal end opening through the instrument body proximal segment and

instrument body distal segment to a stylet distal end, the stylet lumen extending in parallel with and radially offset in a second radial direction from the instrument body distal axis in the instrument body distal segment, and further comprising:

5 inserting a relatively straight stylet wire of a stylet through the stylet lumen proximal end opening and distally through a selected proximal portion of the instrument body distal segment to constrain the formation of the curve to the distal portion of the instrument body distal segment.

10 37. The method of advancing an elongated medical instrument of Claim 36, wherein the step of selectively applying tension further comprises:

applying a hand-held tool to engage the proximal and distal ends of the proximal segment in its relaxed length; and

15 manually manipulating the hand-held tool to apply a selective amount of tension that stretches the proximal segment from its relaxed length to a selected tensioned length that forms a curve of desired radius at least a distal portion of the distal segment.

38. The method of advancing an elongated medical instrument of Claim 34, wherein the step of selectively applying tension further comprises:

20 applying a hand-held tool to engage the proximal and distal ends of the proximal segment in its relaxed length; and

manually manipulating the hand-held tool to apply a selective amount of tension that stretches the proximal segment from its relaxed length to a selected tensioned length that forms a curve of desired radius at least a distal portion of the distal segment.

25 39. The method of advancing an elongated medical instrument of Claim 34, wherein the medical instrument comprises an electrical medical lead.

40. The method of advancing an elongated medical instrument of Claim 34, wherein the medical instrument comprises a guide wire.

41. The method of advancing an elongated medical instrument of Claim 34, wherein the medical instrument comprises a catheter.

42. A system for advancing an elongated medical instrument through the body
5 comprising:
an the elongated medical instrument adapted to be inserted into a pathway of the body,
the elongated medical instrument comprising:
an instrument body extending between an instrument body proximal end and an
instrument body distal end and having an instrument body proximal segment and an
10 instrument body distal segment, the instrument body having an instrument body axis
extending axially in the instrument body distal segment and further comprising an
elongated pull wire lumen extending through the instrument body proximal segment and
instrument body distal segment, the pull wire lumen extending in parallel with and radially
offset in a first radial direction from the instrument body distal axis in the instrument body
15 distal segment;
an inelastic pull wire extending through the pull wire lumen from a pull wire
proximal attachment with the elongated medical instrument to a pull wire distal attachment
with the instrument body distal segment; and
the instrument body proximal segment is formed of an elastic material capable of
20 being stretched axially under axially applied tension; and
tension applying means operable as the distal end is advanced, for selectively applying
tension axially to stretch the instrument body proximal segment whereby the inelastic pull wire
bends in the first radial direction and thereby imparts a curve to the instrument body in the
instrument body distal segment so as to deflect the distal end to the extent found expedient to
25 advance the distal tip and to position the distal end at a remote site in the body.

43. The system of Claim 42, further comprising:
means for selectively restraining the length of the curve imparted in the instrument
body distal segment to effect the advancement and positioning of the distal end.

44. The system of Claim 42, wherein the instrument body further comprises an elongated stylet lumen extending from a stylet lumen proximal end opening through the instrument body proximal segment and instrument body distal segment to a stylet distal end, the stylet lumen extending in parallel with and radially offset in a second radial direction from the instrument body distal axis in the instrument body distal segment, and further comprising:
5 a stylet having a relatively straight stylet wire adapted to be inserted through the stylet lumen proximal end opening and distally through a selected proximal portion of the instrument body distal segment to constrain the formation of the curve to the distal portion of the instrument body distal segment.

10

45. The system of Claim 44, wherein the tension applying means further comprises a hand-held tool adapted to engage the proximal and distal ends of the proximal segment in its relaxed length and having means responsive to manual manipulation to apply a selective amount of tension that stretches the proximal segment from its relaxed length to a selected
15 tensioned length that forms a curve of desired radius at least a distal portion of the distal segment.

46. The system of Claim 42, wherein the tension applying means further comprises a hand-held tool adapted to engage the proximal and distal ends of the proximal segment in its relaxed length and having means responsive to manual manipulation to apply a selective
20 amount of tension that stretches the proximal segment from its relaxed length to a selected tensioned length that forms a curve of desired radius at least a distal portion of the distal segment.

47. The system of Claim 46, wherein the hand-held tool further comprises a frame that supports a fixed cradle adapted to engage one of the first and second ends of the instrument body proximal segment and supports a shuttle movable along the frame with respect to the fixed cradle, the shuttle adapted to engage the other of the first and second ends of the instrument body proximal segment, whereby the shuttle is manually movable along the
25 frame to axially apply tension to and increase the length of the instrument body proximal segment.

30

"0944310340"

48. The system of Claim 47, wherein the hand-held tool further comprises a movable stop supported by the frame in the path of movement of the movable shutter that is adjustable to limit the maximum spacing that can be made between the first and second surfaces.

5

49. The system of Claim 47, wherein the hand-held tool further comprises a spring load that limits the maximum tension that can be applied made between the proximal and distal rings.

10

50. The system of Claim 46, wherein the hand-held tool further comprises first and second elongated spring bands that extend between opposed first and second sides of first and second extension blocks, the first extension block engaging one of the first and second ends of the instrument body proximal segment and the second extension block engaging the other of the first and second ends of the instrument body proximal segment, whereby the first and second extension blocks are spread apart as the elongated spring bands are pressed toward one another to axially apply tension to and increase the length of the instrument body proximal segment.

15

51. The system of Claim 50, wherein the hand-held tool further comprises third and fourth spring bands extending between opposed third and fourth sides of the first and second extension blocks, whereby the first and second extension blocks are spread apart as the first and second elongated spring bands are pressed toward one another and the third and fourth spring bands are pressed toward one another to axially apply tension to and increase the length of the instrument body proximal segment.

20
25

52. The system of Claim 42, wherein the medical instrument comprises an electrical medical lead.

53. The system of Claim 42, wherein the medical instrument comprises a guide wire.

30

0934189 "082104
107280"082104

54. The system of Claim 42, wherein the medical instrument comprises a catheter.